IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MYLAN PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
BAYER INTELLECTUAL PROPERTY GMBH, BAYER AG, and JANSSEN PHARMACEUTICALS, INC.,	)	**CONFIDENTIAL-FILED UNDER SEAL PURSUANT TO D. DEL. LR 26.2**
	)	
Defendants.	)	

COMPLAINT FOR DECLARATORY JUDGMENT
OF PATENT NONINFRINGEMENT

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COMPLAINT FOR DECLARATORY JUDGMENT
OF PATENT NONINFRINGEMENT

Plaintiff Mylan Pharmaceuticals Inc. ("Mylan") hereby brings this action against Defendants Bayer Intellectual Property GmbH ("BIP"), Bayer AG (with BIP, the "Bayer Defendants"), and Janssen Pharmaceuticals, Inc. ("Janssen") (collectively, "Defendants"), seeking a declaration that Mylan has not infringed, does not infringe, and will not infringe any valid claim of U.S. Patent No. 9,415,053 ("'053 patent"). Mylan files this suit to obtain patent certainty under 21 U.S.C. § 355(j)(5)(C)(i) to market its generic rivaroxaban drug product at the earliest possible date.

NATURE OF THE ACTION

1. This action arises under the patent laws of the United States and Amendments to the Federal Food, Drug, and Cosmetics Act ("Hatch-Waxman Act"), which governs the U.S. Food and Drug Administration's ("FDA") approval of both new and generic drugs. 21 U.S.C. § 355 *et seq.* Mylan filed Abbreviated New Drug Application ("ANDA") No. 212220 ("Mylan's ANDA") with FDA seeking approval for Mylan's proposed rivaroxaban tablets ("Mylan's ANDA Product"). Mylan's ANDA contains a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV),

that the ’053 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of Mylan’s ANDA Product.

2. The ’053 patent is listed in FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, (“Orange Book”), as purportedly associated with Xarelto® (rivaroxaban) 2.5 mg tablets.

3. By maintaining the listing of the ’053 patent in the Orange Book, Defendants represent that a claim of infringement of the ’053 patent “could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” 21 U.S.C. § 355(b)(1)(A)(viii).

4. In accordance with 21 U.S.C. § 355(j)(2)(B), by letters dated December 12, 2018 and June 21, 2022, Mylan timely notified Defendants (the “Notice Letters”) that Mylan’s ANDA had been filed with a paragraph IV patent certification for the ’053 patent and provided an Offer of Confidential Access to Mylan’s ANDA.

5. In accordance with 21 U.S.C. § 355(j)(2)(B), Mylan’s Notice Letters included detailed statements of the factual and legal bases for the paragraph IV patent certification for the ’053 patent in connection with Mylan’s ANDA.

6. Defendants chose not to bring an action against Mylan for infringement of the ’053 patent within the 45-day period under 21 U.S.C. § 355(j)(5)(B)(iii).

7. The Hatch-Waxman Act provides for a “civil action to obtain patent certainty” when a generic applicant makes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV). 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)-(cc). This declaratory judgment provision in the Hatch-Waxman Act aims to encourage early resolution of patent disputes, and prevent brand-name drug companies from

using tactics that forestall the competing generic drug makers from entering the market. *See Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1285 (Fed. Cir. 2008).

8. Both requirements are met for the declaratory judgment action expressly authorized by the Hatch-Waxman Act: (1) the 45-day period has passed without Defendants bringing an action for infringement of the '053 patent against Mylan, and (2) Mylan made the statutory offer of confidential access in connection with the '053 patent. 21 U.S.C. § 355(j)(5)(C)(i).

9. Mylan's Complaint seeks a judgment to obtain patent certainty that Mylan's ANDA Product does not infringe any valid and enforceable claim of the '053 patent. The judgment would allow Mylan to obtain final approval of ANDA No. 212220 upon expiry of the pediatric exclusivity for U.S. Patent No. 7,157,456 ("'456 patent") on February 28, 2025 and enable Mylan to bring Mylan's ANDA Product to market at the earliest possible date allowed under applicable statutory and FDA regulatory provisions.

THE PARTIES

10. Mylan is a corporation organized and existing under the laws of the State of West Virginia with its principal place of business at 3711 Collins Ferry Road, Morgantown, West Virginia 26505.

11. On information and belief, BIP is a foreign corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Alfred-Nobel-Strasse 10, 40789 Monheim am Rhein, Germany.

12. On information and belief, Bayer AG is a foreign corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Kaiser-Wilhelm-Allee 1, 51368 Leverkusen, Germany.

13. On information and belief, Janssen is a domestic corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

JURISDICTION AND VENUE

14. This action is for declaratory judgment that Mylan has not, does not, and will not infringe the claims of the '053 patent. This action arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, the Hatch-Waxman Act, 21 U.S.C. §§ 355(j) *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

15. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action involves substantial claims arising under the United States Patent Act, 35 U.S.C. §§ 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, 21 U.S.C. § 355(j)(5)(C), and 35 U.S.C. § 271(e)(5).

16. There is an actual controversy between Mylan and Defendants concerning noninfringement of the '053 patent arising under the United States Patent Act, 35 U.S.C. §§ 1 *et seq.* and Mylan's right to continue to seek approval by FDA of Mylan's ANDA No. 212220, and upon FDA approval, to market Mylan's ANDA Product.

17. This Court has personal jurisdiction over the Bayer Defendants at least because personal jurisdiction can be established through service of summons or waiver of service of summons under Fed. 4. Civ. P. 4(k)(2).

18. This Court has personal jurisdiction over the Bayer Defendants at least because, on information and belief, the Bayer Defendants transact business within the State of Delaware and/or have engaged in continuous and systemic contacts with the State of Delaware. On information

and belief, the Bayer Defendants regularly and continuously transact business within Delaware, either directly or through their affiliates and/or agents.

19. On information and belief, Bayer AG has registered to do business in the State of Delaware and has appointed a registered agent in Delaware to accept service of process.

20. This Court has personal jurisdiction over the Bayer Defendants at least because the Bayer Defendants, on information and belief, (1) directly or indirectly formulate pharmaceutical products that are marketed and sold throughout the United States and in this judicial district and (2) have consented to personal jurisdiction in this judicial district by filing suits in this judicial district, including but not limited to suits relating to Xarelto® (rivaroxaban): *Bayer Intellectual Property GmbH et al. v. Aurobindo Pharma Limited et al.*, C.A. No. 15-cv-00902; *Bayer Intellectual Property GmbH et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 17-cv-00584; and *In re: Xarelto (Rivaroxaban) ('310) Patent Litigation*, 21-md-03017, thereby having availed themselves of the rights and benefits of Delaware law. On information and belief, the Bayer Defendants have conducted and continue to conduct business in this judicial district, and this judicial district is a destination of pharmaceutical products the Bayer Defendants directly or indirectly developed.

21. This Court has personal jurisdiction over the Bayer Defendants at least because Bayer AG filed two patent infringement lawsuits against Mylan in the U.S. District Court for the Northern District of West Virginia relating to Mylan's ANDA Product and moved to transfer both suits to this Court for coordinated and consolidated pretrial proceedings with other actions already pending before this Court that Bayer chose to file in this judicial district. Both suits, *Bayer Pharma AG et al. v. Mylan Pharmaceuticals Inc. et al.*, Case Nos. 21-cv-99 and 22-cv-63 (N.D.W. Va.), were transferred by the multidistrict litigation panel to this Court at Bayer's request. In doing so

Bayer AG availed itself of the rights and benefits of Delaware law and this Court in relation to Mylan's ANDA Product.

22. Exercising personal jurisdiction over the Bayer Defendants in this judicial district would not be unreasonable given the Bayer Defendants' contacts with this judicial district and this judicial district's interest in resolving disputes related to Xarelto® (rivaroxaban) 2.5 mg tablets and Mylan's ANDA Product.

23. This Court has personal jurisdiction over Janssen at least because, on information and belief, Janssen transacts business within the State of Delaware and/or has engaged in continuous and systemic contacts with the State of Delaware, including conducting substantial and regular business therein through marketing and sales of pharmaceutical products in Delaware including, but not limited to, Xarelto® (rivaroxaban) 2.5 mg tablets. On information and belief, Janssen is registered with the State of Delaware's Board of Pharmacy as a wholesaler and distributor/manufacturer under License Nos. A4-0002379 and DM-0011940. On information and belief, Janssen purposefully has conducted and continues to conduct business in this judicial district.

24. This Court has personal jurisdiction over Janssen at least because Janssen, on information and belief, (1) directly or indirectly markets and sells pharmaceutical products throughout the United States and in this judicial district and (2) has consented to personal jurisdiction in this judicial district by filing suits in this judicial district, including, but not limited to suits relating to Xarelto® (rivaroxaban): *Bayer Intellectual Property GmbH et al. v. Aurobindo Pharma Limited et al.*, C.A. No. 15-cv-00902; *Bayer Intellectual Property GmbH et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 17-cv-00584; and *In re: Xarelto (Rivaroxaban) ('310) Patent Litigation*, 21-md-03017, thereby having availed itself of the rights and benefits of Delaware law.

On information and belief, Janssen has conducted and continues to conduct business in this judicial district, and this judicial district is a destination of Janssen's pharmaceutical products.

25. This Court has personal jurisdiction over Janssen at least because Janssen filed two patent infringement lawsuits against Mylan in the U.S. District Court for the Northern District of West Virginia relating to Mylan's ANDA Product and moved to transfer both suits to this Court for coordinated and consolidated pretrial proceedings with other actions already pending before this Court that Janssen chose to file in this judicial district. Both suits, *Bayer Pharma AG et al. v. Mylan Pharmaceuticals Inc. et al.*, Case Nos. 21-cv-99 and 22-cv-63 (N.D.W. Va.), were transferred by the multidistrict litigation panel to this Court at Janssen's request. In doing so, Janssen availed itself of the rights and benefits of Delaware law and this Court in relation to Mylan's ANDA Product.

26. Exercising personal jurisdiction over Janssen in this judicial district would not be unreasonable given Janssen's contacts with this judicial district and this judicial district's interest in resolving disputes related to Xarelto® (rivaroxaban) 2.5 mg tablets and Mylan's ANDA Product.

27. For at least the reasons set forth above in paragraphs 11-26, including, for example, that the Bayer Defendants are foreign entities, venue is proper in this judicial district under 28 U.S.C. §§ 1391, 1400, and/or 21 U.S.C. § 355.

FACTUAL BACKGROUND

28. On information and belief, Janssen holds New Drug Application No. 022406 for rivaroxaban tablets, referred to as Xarelto®.

29. On its face, the '053 patent, titled "Solid, Orally Administrable Pharmaceutical Composition" issued on or about August 16, 2016. The '053 patent is attached as Exhibit A.

30. On information and belief, BIP is the assignee of the '053 patent.

31. On information and belief, Bayer AG is an exclusive licensee under the ’053 patent.

32. On information and belief, Janssen is an exclusive sublicensee under the ’053 patent.

33. The ’456 patent that protects the rivaroxaban compound expires on August 28, 2024, and its pediatric exclusivity will expire February 28, 2025.

34. Mylan’s ANDA contains a paragraph III patent certification for the ’456 patent.

35. Thus, Mylan cannot sell its ANDA Product until after expiry of pediatric exclusivity, February 28, 2025.

36. The ’053 patent will expire November 13, 2024, and its pediatric exclusivity will expire May 13, 2025.

37. In the absence of a judgment of non-infringement of the ’053 patent prior to November 13, 2024, Mylan will be unable to obtain final approval for ANDA No. 212220 until after the May 13, 2025 expiry of pediatric exclusivity even though Defendants have never asserted the ’053 patent against Mylan. Mylan received tentative approval for ANDA No. 212220 on June 27, 2022.

38. To obtain patent certainty and secure timely approval of ANDA No. 212220 at the earliest possible date, Mylan seeks a judgment that Mylan’s ANDA Product does not infringe any valid and enforceable claim of the ’053 patent. Defendants’ actions have resulted in a substantial controversy regarding the ’053 patent between Mylan and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that the ’053 patent is not and will not be infringed.

COUNT I
Declaratory Judgment of Noninfringement of the ’053 Patent

39. Mylan repeats and incorporates by reference each of the foregoing paragraphs 1-38 of the Complaint.

40. The ’053 patent issued with 24 claims. Claims 1 and 6 are the only independent claims in the ’053 patent.

41. Independent claim 1 of the ’053 patent recites:

> A process for the preparation of a solid, orally administrable pharmaceutical composition comprising an active compound (I) that is 5-chloro-N-({(5S)-2-oxo-3-[4-(3-oxo-4-morpholinyl)-phenyl]-1,3-oxazolidin-5-yl}-methyl)-2-thiophenecarboxamide in hydrophilized form, comprising the following steps:
>
> (a) first preparing granules comprising the active compound (I) in hydrophilized form using fluidized bed granulation for moist granulation;
>
> (b) and converting the granules into the pharmaceutical composition.

42. Independent claim 6 of the ’053 patent recites:

> A solid, orally administrable pharmaceutical composition comprising an active compound (I) that is 5-chloro-N-({(5S)-2-oxo-3-[4-(3-oxo-4-morpholinyl)-phenyl]-1,3-oxazolidin-5-yl}-methyl)-2-thiophenecarboxamide in hydrophilized form prepared by a process comprising the following steps:
>
> (a) first preparing granules comprising the active compound (I) in hydrophilized form using fluidized bed granulation for moist granulation;
>
> (b) and converting the granules into the pharmaceutical composition.

43. Dependent claims 2-5 and 7-24 of the ’053 patent incorporate all limitations of claims 1 or 6 by virtue of their direct or indirect dependency therefrom.

44. Each claim of the ’053 patent requires “first preparing granules comprising the active compound (I) in hydrophilized form using fluidized bed granulation for moist granulation.”

45. Mylan’s ANDA Product is not prepared by “first preparing granules comprising the active compound (I) in hydrophilized form using fluidized bed granulation for moist granulation,” as required by each claim of the ’053 patent.

46. The process for manufacturing Mylan's ANDA Product is set forth in Module 3.2.P.3.3 of Mylan's ANDA, which is attached as Exhibit B.

47. Mylan's ANDA Product is manufactured using the process described in Exhibit B.

48. Mylan's ANDA Product is prepared by using high shear granulation. Exhibit B at 2.

49. The granulation step for manufacturing Mylan's ANDA Product is described as "High Shear Granulation." *Id.*

50. The granulation step for manufacturing Mylan's ANDA Product uses a Vector GMX75 Mixer or a Gral-150 High Intensity Granulator. *Id.* at 2, 4.

51. The granulation step for manufacturing Mylan's ANDA Product does not use fluidized bed granulation. *Id.*

52. Mylan's ANDA Product does not literally meet each and every limitation of claims 1-24 of the '053 patent.

53. Mylan's ANDA Product does not literally infringe any valid, enforceable claim of the '053 patent.

54. The claims of the '053 patent are not entitled to any scope of equivalents for the claimed manufacturing process.

55. The specification of the '053 patent states "[t]he moist granulation in process step (a) can be carried out in a mixer (=mixer granulation) or in a fluidized bed (=fluidized bed granulation); fluidized bed granulation is preferred." Exhibit A at 2:48-50.

56. The specification of the '053 patent explains and exemplifies that high shear granulation with a mixer and fluidized bed granulation are different processes.

57. Each claim of the ’053 patent requires first preparing granules comprising rivaroxaban in hydrophilized form using fluidized bed granulation for moist granulation. Exhibit A at 8:55-10:37.

58. No claim of the ’053 patent encompasses preparing granules comprising rivaroxaban using high shear mixing.

59. During prosecution of the ’053 patent, in response to obviousness rejections over prior art (attached as Exhibit C), the applicants argued that “a tablet produced by moist granulation using fluidized bed granulation had significantly higher bioavailability than a tablet produced by moist granulation using a high shear mixer. This improvement using fluidized bed granulation compared to high shear mixing is surprising and unexpected, and overcomes a *prima facie* case of obviousness.” September 21, 2015 Amendment/Request for Reconsideration at 9 (attached as Exhibit D) (hereinafter, “Granulation Arguments”).

60. Applicants submitted an inventor declaration and evidence of experiments to substantiate their Granulation Arguments. *Id.* at 13-19. In the declaration, named inventor Klause Benke stated, “preparing compositions comprising rivaroxaban in hydrophilized form using a fluidized bed granulation process yields a composition with surprisingly superior bioavailability as compared to both compositions made using direct tableting and compositions prepared using a high shear mixer.” *Id.* at 18.

61. The USPTO relied on the applicants’ Granulation Arguments in allowing the claims of the ’053 patent. Notice of Allowance, November 12, 2015 (attached as Exhibit E).

62. As a result of at least the Granulation Arguments, Defendants are estopped from asserting that high shear granulation is equivalent to the claimed fluidized bed granulation.

63. As a result of at least the Granulation Arguments, the applicants for the ’053 patent disclaimed any claim scope encompassing high shear granulation.

64. The prosecution of the ’053 patent, including at least the Granulation Arguments, evinces a clear and unmistakable surrender of high shear granulation.

65. Mylan’s ANDA Product does not meet each and every limitation of any of claims 1-24 of the ’053 patent under the doctrine of equivalents.

66. More than forty-five (45) days have elapsed since Defendants’ receipt of Mylan’s Notice Letters.

67. To date, Defendants have not sued Mylan for infringement of the ’053 patent.

68. Mylan has not infringed, does not infringe, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly, any valid, enforceable claim of the ’053 patent, including for at least the reasons set forth in Mylan’s Notice Letters.

69. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Mylan’s ANDA Product will not constitute infringement, either literally or under the doctrine of equivalents, directly or indirectly, of any valid, enforceable claim of the ’053 patent.

70. Mylan’s ANDA Product will not infringe any valid and/or enforceable claim of the ’053 patent at least because Mylan’s ANDA Product does not satisfy the claims of the ’053 patent, either literally or under the doctrine of equivalents.

71. Mylan is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Mylan’s ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the ’053 patent.

PRAYER FOR RELIEF

WHEREFORE, Mylan respectfully requests that the Court enter judgment as follows:

A. The submission of ANDA No. 212220 does not constitute infringement of any claim of the ’053 patent, either literally or under the doctrine of equivalents;

B. The commercial manufacture, use, sale, offer for sale, and/or importation of Mylan’s ANDA Product does not and will not infringe any claim of the ’053 patent, either literally or under the doctrine of equivalents;

C. Defendants, their officers, agents, servants, employees, attorneys, successors, and any person who acts in concert or participation with Defendants be preliminarily and permanently enjoined from using the ’053 patent to block, hamper, hinder, or obstruct FDA approval of ANDA No. 212220;

E. Mylan be awarded attorneys’ fees due to Defendants’ failure to resolve the parties’ dispute, causing Mylan to be forced to bring this suit; and

F. Mylan be awarded such other and further relief as the Court deems just and proper, including any appropriate relief under 35 U.S.C. § 285.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

By: */s/ David E. Moore*

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